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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097139,155	08/24/98	FLYNN	D 960565.ORI

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EXAMINER

GUSHI, R

ART UNIT PAPER NUMBER

2833

DATE MAILED: 02/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/139,155

Applicant(s)

Flynn et al.

Examiner

Gushi, Ross

Group Art Unit

2833

☒ Responsive to communication(s) filed on Jan 24, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-15 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 through 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stutz, Jr., ("Stutz") in view of Fain et al. U.S. No. 5,679,026 ("Fain").
3. Stutz teaches a lead 32 comprising an elongated, flexible, electrically insulating main body portion having a proximal and distal end, at least one terminal connector attached to the proximal end of the main body and adapted for coupling the lead to a header assembly of an implantable medical device, at least one electrode embodied within a distal end portion of the main body portion, and at least one conductor corresponding with each electrode and electrically insulated by the main body portion, wherein a distal end of each conductor is attached to each corresponding electrode and a proximal end of each conductor is attached to at least one corresponding terminal connector.
4. Stutz does not teach an adapting member.
5. Fain teaches an adapter capable of electrical and mechanical coupling to a port of an implantable medical device's header and to a plurality of leads, said adapter comprising:

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- a. A terminal connector attached to a proximal end of a main body and adapted for coupling the adapter to a header assembly of an implantable medical device;
  - b. A conductor corresponding to an electrode of a connected lead and insulated by the main body of the adapter where the conductor is attached to a corresponding terminal connector.
6. The adaptor connects to leads and has a plurality of ports adaptable for sealably receiving a terminal connector of a plurality of leads, wherein each port has a conductive terminal block positioned within each port and wherein a jumper wire embedded within the adapter interconnects the terminal block with one of the conductors insulated by the main body of the lead. (Col. 8, lines 25-30: "In this embodiment, two . . . leads are brought together by the header adapter 40 from the connector ports 42, 44 to a single in-line . . . connector 50." Col. 8, lines 48-53: "The lead connector block 64 and the lead connector block (not shown) opposite thereto, are both electrically connected to the lead connector 50 . . . in a manner well-known in the art, e.g., by electrical wires . . . ." See also Col. 10, lines 30-45).
7. Fain discusses and assumes the leads which are pluggable into the adapter and which are well known in the art and which have an elongated insulated main body portion having a proximal end and a distal end, and an electrode at the distal end of the main body and a lead connector at the proximal end.
8. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the Fain adapter and the Stutz lead into a unitary lead and adapter. The use of

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a one piece construction instead of the two piece lead and adapter construction would have been a matter of obvious engineering choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

9. Per claim 2, in the combination of the Fain adapter and a lead, the adapting member is positioned on the lead adjacent to the proximal end of the main body of the lead.

10. Per claims 3, 10, the Fain adapter engages the header assembly of the implantable medical device.

11. Regarding claims 4, 5, 11, 12, the Fain device does not have an aperture extending therethrough. Rather, the Fain device has lead connector port 46 electrically connected to lead connector 52. At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the Fain device could be modified such that the lead connector port 46 and the lead connector 52 could be replaced by an aperture through the adapter so that the adapter would not interfere with another lead connected directly to a port on the header. Alternatively, given that as disclosed, the aperture is merely to allow a lead terminal connector to plug directly into a port on the header, the inclusion of an aperture would have been a modification of the shape of the adapter which a person of ordinary skill in the art would have found obvious given the absence of persuasive evidence that the particular claimed configuration is significant. The shape of the Fain adapter could have been modified in any number of obvious ways so that the shape of the adapter would not interfere with other leads being connected directly to the header.

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12. Per claims 6, 13, the adapting member is contoured to conform to the shape of the header assembly.

13. Per claims 7, 14, the adaptor is suitable for receiving the terminal end of a uni-polar lead.

14. Regarding claims 8, 15 at the time of the invention, it would have been obvious to a person of ordinary skill in the art to use electrical wire having an outer insulating layer and an inner conductive wire for the jumper wire, such wire being well known and commonly used in the art.

#### ***Response to Arguments***

15. Applicant's arguments filed 1/24/00 have been fully considered but they are not persuasive.

16. Applicant argues that Stutz does not suggest combining a lead and adapter. The examiner maintains that the use of a one piece construction instead of the two piece lead and adapter construction would have been a matter of obvious engineering choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

17. Applicant argues that Fain serves a different purpose. The examiner disagrees and regardless, the argument is fails to distinguish the device as claimed.

18. Applicant argues that Fain does not teach the modification suggested. The examiner maintains that the use of a one piece construction instead of the two piece lead and adapter

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construction would have been a matter of obvious engineering choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

19. Applicant argues that hindsight has been used. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

20. Applicant argues that the references do not show a jumper wire. The examiner disagrees. See Fain, Col. 8, lines 25-30: "In this embodiment, two . . . leads are brought together by the header adapter 40 from the connector ports 42, 44 to a single in-line . . . connector 50." Col. 8, lines 48-53: "The lead connector block 64 and the lead connector block (not shown) opposite thereto, are both electrically connected to the lead connector 50 . . . in a manner well-known in the art, e.g., by electrical wires . . . ." See also Col. 10, lines 30-45.

### ***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ross Gushi whose telephone number is (703) 306-4508.

February 15, 2000

rng

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